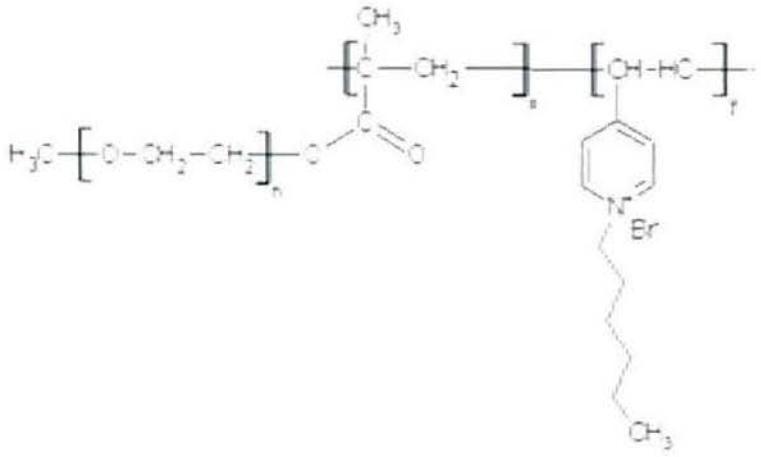
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)
November 18, 2016

EPA Reg#: 91413-E		DP Barcode: 436724	
		Submission #: 993463	E-Sub#:
Product name: **Nouvex N950 Master Batch**		Registrant: Poly Group LLC	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date: 11/22/16		PSB received date: 11/14/16	
CTT received date: 11/14/16		Science-received date: 11/14/16	
Formulation type: EUP			
Integrated system: [x]	Non-integrated -system: []	Food use: []	Non-food use: [x]
Action Code: A420		Date Completed: November 18, 2016	

PC Code	CAS #	Active Ingredient Names	% wgt (label)
012309	1471991-40-8	Pyridine, 4-ethenyl-, polymer with a-(2-methyl-1-oxo-2-propen-1-yl)-w-methoxypoly(oxy-1 ,2-ethanediyl),compd. with 1-bromohexane	30.0



Test Lab: Poly Group LLC	
MRID(s): 49553201 (50087201) & 49553202 (50087201)	
Approver: Karen P. Hicks	Approved date: November 18, 2016
Guideline: OPPTS Guideline, Series 830 groups "A & B"	
Comments:	

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MEMORANDUM:

Subject:	Product Chemistry Review for EPA Reg # 91413-E Product name: **Nouvex N950 Master Batch** DP#: 436724
From:	Salvador Rodriguez, Chemist Product Science Branch, CT Team Antimicrobials Division (7510P)
Thru:	Karen P. Hicks, CT Team Leader JB for KPH Product Science Branch Antimicrobials Division (7510P)
To:	Eric Miederhoff PM Team 31 Antimicrobials Division (7510P)
APPLICANT:	Poly Group LLC
Action code:	A420
Due date:	08/22/15

Product Formulation
Active Ingredient

	% by wt
Pyridine, 4-ethenyl-, polymer with a-(2-methyl-1-oxo-2-propen-1-yl)-w-methoxypoly (oxy-1, 2-ethanediyl),compd. with 1-bromohexane	30.0

BACKGROUND:

The registrant, Poly Group LLC., has submitted a Confidential Statement of Formula, for the basic and the OPPTS Guideline Series 830 Groups "A & B", to support the registration for the new product with new active ingredient (AI) **Nouvex N950 Master Batch.** The product chemistry reviewer has reviewed the following documents:

- Transmittal letter, dated 11/10/16.
- Data matrix, dated 11/14/16
- Confidential Statement of Formula, dated 10/14/16, for the basic formulation.
- Draft label, dated 10/14/16.
- Study titled: "Product Chemistry for **Nouvex N950 Master Batch** groups A & B". MRID #s: 49553201 & 49553202. 50087201 & 50087202.
- Confidential Statement of Formula, dated 01/28/15, for the basic formulation. Reference

FINDINGS:

1. The CSF, dated 01/28/16, for the basic formulation is revised.

2. The CSF and the label have the same nominal concentration for the active ingredient (AI).

3. All certified limits meet the 40 CFR, EPA standard certified limits.

4. The OPPTS Guidelines Series 830 Group A product chemistry data requirements applicable to end-use products have been met. MRID # 49553201& 50087201.

5. The OPPTS guidelines series 830 Group B product chemistry data requirements applicable to manufactured-use products have been met, with the exception of the series 830.6317 & 830.6320. MRID #49553202 & 50087202.

5. The registrant indicated that these courtesy five pilot-scale batches for the product; **Nouvex N950 Master Batch** were selected for performing the Preliminary Analysis Study. Using the Enforcement Analytical Method, samples were analyzed in duplicate and the average of the five readings was used to express the weight % active ingredient (AI) in each sample. The results are the following:

Lot #	Average content in Wgt (%) Wgt (%) of Nouvex N950 Master Batch
N950-13172-A	30.40
N950-14052-A	30.53
N950-14071-A	30.65
N950-14098-	31.14
N950-14154-A	30.61
Average:	**30.666**

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the proposed CSF for the basic formulation, dated 10/14/16 and the OPPTS Guideline Series 830 Groups "A & B" supporting the antimicrobial, integrated, non-food use, manufacture-use product **91413-E to be acceptable,** with the exception of the 830.6317 "Storage Stability & 830.6320 " Corrosion Characteristics" Studies. The results of the five batch analysis OPPTS 830.1700 are within the EPA standards certified limits.

CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [x]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [ ]

c. Physical state of product: *Powder crystals*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Pyridine, 4-ethenyl-, polymer with a-(2-methyl-1-oxo-2-propen-1-yl)-w-methoxypoly (oxy-1, 2-ethanediyl),compd. with 1-bromohexane	30.00	28.5	31.5

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [X] No [ ] Not applicable [ ]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No []

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [X]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49553201 50087201
830.1600 Description of Materials	A	49553201 50087201
830.1620 Production Process[2]	A	49553201 50087201
830.1650 Formulation Process[3]	NA	
830.1670 Formation of Impurities[4]	A	49553201 50087201
830.1700 Preliminary Analysis[5]	A	49553201 50087201
830.1750 Certified Limits[6]	A	49553201 50087201
830.1800 Enforcement Analytical Method[7]	A	49553201 50087201
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for manufacturing-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Buff	49553202
830.6303 Physical State	A	Plastic pellets(crystals)	49553202 50087202
830.6304 Odor	A	Slightly faint, polymer-like	49553202 50087202
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	A	*Nouvex Technical Antimicrobial Polymer* will not come into contact with metals during its storage and use, therefore waiver for stability to metals and meal ions is requested	49553202 50087201
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Compatible with water, 10% monoammonium phosphate solution, iron powder, and kerosene. Incompatible with 10% potassium permanganate solution.	49553202 50087201
830.6315 Flammability/ Flame Extension	A	Product has no capacity to initiate or support combustion. All of its constituents are inorganic, and none pyrophoric.	49553202 50087202
830.6316 Explodability	W	Waiver of this requirement is requested. Product has no potential to act as an explosive, because none of its ingredients contain organically-bonded nitro groups or other functional groups that might confer this hazard.	49553202 50087201
830.6317 Storage Stability	G	Study in progress.	
830.6319 Miscibility[1]			

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
	W	Waiver of this requirement is requested. Per the Guideline, this information is required when the product is an emulsifiable liquid and is to be diluted with petroleum solvent. Product is a solid, so this parameter is not relevant.	49553202 50087201
830.6320 Corrosion Characteristics	G	Study in progress	
830.6321 Dielectric Breakdown Voltage	W	Waiver of this requirement is requested. Product is not a liquid. Data on the dielectric breakdown voltage of the product is neither relevant nor required.	49553202 50087201
830.7000 pH[2]	A	3-4 at 20°C	49553202 50087202
830.7050 UV/Visible Absorption	NA	Wavelength (nm) *E*1 *cm* 1% Specific Absorbance (calculated) Acidic (pH = 1.20) 203.3 343.785 228.9 188.418 Neutral (pH = 6.12) 197.2 659.040 228.8 188.418 Alkaline (pH = 12.41) 209.9 138.136 233.6 125.424	49553202 50087201
830.7100 Viscosity	A	The product is a solid crystals	50087202 49553202
830.7200 Melting Point/Melting Range	A	None observed; the substance decomposes before melting occurs.	49553202 5008/7201
830.7220 Boiling Point/Boiling Range	A	Waiver is requested. *Nouvex Technical Antimicrobial Polymer* is a solid.	49553202 50087201
830.7300 Density/Relative Density/Bulk Density	A	Pour density: 0.635 g/mL at 20°C Tap density: 0.663 g/mL at 20°C	49553202 50087201
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*Nouvex Technical Antimicrobial Polymer* is known to have a significant solubility in water; therefore the "Shake flask method" is the most appropriate testing method.	49553202 50087201
830.7520 Particle size, fiber length & diameter distribution	A	If water soluble, not required.	

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- Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water